

REMARKS

Upon entry of the amendments described above, claims 14 to 18, 20, and 22 to 68 will be pending. Applicants propose to amend claim 14 to recite the claimed apparatus with even more particularity and to add language that tracks language of claim 26. Applicants also propose to amend claims 38 and 40 to be in independent form and claims 15, 17, and 18, to comport with the language of amended claim 14. Applicants also propose to add new claims 57 to 68. Support for the amendments and new claims can be found throughout the specification, e.g., at page 2, column 2, paragraph [0027], and page 3, column 2, paragraph [0037], of the published application (U.S. Publication No. 2006/0093681). The amendments and new claims add no new matter to the application.

Interview Summary

Applicants thank Examiner Nasser for taking the time to conduct an interview with the undersigned on June 26, 2008. The rejection of claim 14 was discussed. Applicants do not agree that Otterbein et al. (U.S. Publication No. 2004/0258772; hereinafter "Otterbein") anticipates this claim. However, in the interest of moving the present application toward allowance, applicants proposed amendments along the lines described above. Examiner Nasser suggested, but did not promise, that such amendments might overcome the anticipation rejection, but suggested that further searching might be needed. Applicants have therefore filed the present Reply along with a Request for Continued Examination (RCE).

Claim Objections and Allowed Claims

Claims 23, 24, 29, 30, 38 and 40 were objected to for depending from rejected claims but, according to the Office, would be allowable if redrafted into independent form to incorporate the elements of all intervening claims. Applicants have amended claims 38 and 40 to be in independent form as requested by the Office. With respect to claims 23, 24, 29 and 30, applicants point out that they have, in the interest of moving the present application toward

allowance, amended the claims from which these depend. Applicants therefore request that the objections against these claims be withdrawn and that the claims be found allowable.

Applicants acknowledge the Office's conclusions that: claims 43 to 56 are allowable; claims 23 and 29 define over the art in that none of the art monitors CO concentration from levels of oxyhemoglobin; claims 24 and 30 define over the art of record in that none of the art monitors CO levels by monitoring enzyme activity in the blood; claims 38 and 43 to 56 define over the art in that none of the art delivers CO to the patient in pulses that are triggered by inhalation or exhalation; and claim 40 defines over the art in that none of the art delivers CO to the patient in pulses based on the CO concentration (see Office Action at page 5).

Information Disclosure Statement

Applicants note that in the non-final Office Action dated June 22, 2007, the Office returned initialed copies of applicants' Information Disclosure Statements (IDS) filed on January 3, 2005 and June 15, 2006. All references cited were initialed in those copies except WO 2002/056931, which was cited in the IDS filed on January 3, 2005 as reference AL. No initials appear by the side of that reference. Applicants therefore respectfully request that the Office initial reference AL and return a copy to applicants as soon as possible.

Rejection under 35 U.S.C. §102

Claims 14-17, 22, 25-28, 31, 35, 36, 37, 39, 41 and 42 were rejected as allegedly anticipated by Otterbein. Applicants respectfully traverse for the reasons below.

As an initial matter, applicants point out that although they do not agree that Otterbein anticipates claim 14 as originally filed, they have in the interest of moving this application toward allowance amended claim 14 to recite the claimed apparatus with even more particularity. Otterbein does not anticipate amended claim 14 because it does not describe an apparatus as recited in this claim. The paragraph of Otterbein (paragraph 0069) to which the Office points in support of the rejection states:

In a hospital setting, the gas presumably will be delivered to the bedside where it will be mixed with oxygen or house air in a blender to a desired concentration in ppm (parts per million). The patient will inhale the gas mixture through a ventilator, which will be set to a flow rate based on patient comfort and needs.

This is determined by pulmonary graphics (i.e., respiratory rate, tidal volumes, etc.). Fail-safe mechanism(s) to prevent the patient from unnecessarily receiving greater than desired amounts of carbon monoxide can be designed into the delivery system. The patient's carbon monoxide level can be monitored by studying (1) carboxyhemoglobin (COHb), which can be measured in venous blood, and (2) exhaled carbon monoxide collected from a side port of the ventilator. Carbon monoxide exposure can be adjusted based upon the patient's health status and on the basis of the markers.

Amended claim 14, on the other hand, recites:

An apparatus for administering carbon monoxide to a patient, the apparatus comprising a delivering unit, a carbon monoxide source connected to the delivering unit, a dosing unit connected to the delivering unit and carbon monoxide source, wherein the mass flow between the delivering unit and the carbon monoxide source is controlled by the dosing unit, at least one sensor unit that determines the concentration of carbon monoxide in the patient's blood, and a control unit in communication with the sensor unit and the dosing unit, wherein the control unit regulates the dosing unit depending on feedback from the sensor unit, and wherein the control unit automatically compares the actual concentration of carbon monoxide in the blood with a preset desired value, and regulates the dosing unit to adjust the amount of carbon monoxide delivered to the patient to obtain a concentration in the blood corresponding to the preset desired value.

Otterbein fails to anticipate amended claim 14 because, *inter alia*, it fails to teach numerous elements recited in this claims. For example, nowhere does Otterbein describe a control unit in communication with a sensor unit and a dosing unit. It therefore also follows that Otterbein does not teach that such a control unit regulates the dosing unit based on sensor unit feedback or that the control unit compares the actual concentration of carbon monoxide in a patient's blood with a preset desired value, and regulates the dosing unit to adjust the amount of carbon monoxide delivered to the patient to obtain a concentration in the blood corresponding to the preset desired value. Accordingly, Otterbein does not anticipate claim 14 because it does not teach every limitation recited in the claim. For the same reason, Otterbein fails to anticipate claims 13-17, 22, 25-28, 31, 35, 36, 37, 39, 41 and 42, which depend from claim 14. Applicants therefore request that the present rejection be reconsidered, withdrawn, and not applied to new claims 57 to 64, which ultimately depend from claim 14 (claims 65 to 68 depend from claim 43, which the Office has already indicated is allowable).

Rejection Under 35 U.S.C. §103 (a)

Claim 18 was rejected as allegedly obvious over Otterbein. According to the Office Action (at page 3):

Claim 18 is rejected in it would have been obvious activate an alarm an alarm when the CO concentration exceeded a limit, to alert medical personnel of potential hazardous conditions.

Applicants respectfully traverse. Claim 18 depends from claim 14, the deficiencies of which were discussed above. Claim 18 recites the additional element that at least one sensor unit is connected to an alarm unit. As discussed above, Otterbein does not teach or suggest all of the elements of the apparatus recited in claim 14, much less those of an apparatus that includes an alarm unit as recited in claim 18. Otterbein therefore does not render the presently claimed apparatus obvious because neither it, nor any other art cited by the Office, discloses or suggests all of the elements recited in claim 18. Because Otterbein does not disclose the apparatus recited in claim 14, it would not have been possible for a skilled practitioner to modify Otterbein as suggested by the Office. Thus, applicants submit that a *prima facie* case of obviousness against the present claims has not been established and request that the present rejection be reconsidered, withdrawn, and not applied to the new claims.

Claim 20 was rejected as allegedly obvious over Otterbein in view of Stenzler et al. (U.S. Publication No. 2004/0084048). Stenzler was filed on May 12, 2003 and claims priority, as a continuation-in-part application, to U.S. Serial No. 10/259,997, which was filed on September 27, 2002. The present application was filed internationally on June 23, 2003, and claims priority to German Patent Application Serial No. 10230165.4, filed on July 4, 2002. Applicants again thank Examiner Nasser for discussing this issue with the undersigned. During the interview, applicants pointed out that applicants' priority document was filed in English. Accordingly, no certified translation of this document should be necessary. As requested by Examiner Nasser, applicants submit herewith for his review Exhibit A, which is a copy of German Patent Application Serial No. 10230165.4. Applicants therefore submit that Stenzler is not prior art against the present application for this and the other reasons set forth by applicants in their Reply

to Action of June 22, 2007. Applicants request that the present rejection be reconsidered and withdrawn.

Claims 32 and 33 were rejected under 35 U.S.C. 103(a) as allegedly obvious over Otterbein in view of Aldrich, U.S. Patent No. 5,810,723. Applicants respectfully traverse. Claims 32 and 33 depend from claim 14. The deficiencies of Otterbein with respect to claim 14 were discussed above in detail. Aldrich does not remedy those deficiencies. Aldrich describes, *inter alia*, a non-invasive device and method for detecting possible carbon monoxide poisoning by determining the percentage of carboxyhemoglobin in a subject's blood (see Aldrich at col. 1, lines 6 to 10). Aldrich does not provide the information missing from Otterbein. Aldrich would not have provided skilled practitioners with any motivation or reason to modify Otterbein in an attempt to arrive at the present invention, and apparently Aldrich is not relied upon by the Office for such a teaching. Thus, the combination of Otterbein and Aldrich do not support a *prima facie* case of obviousness and the rejection should be withdrawn.

Claim 34 was rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Otterbein in view of Stone, U.S. Patent No. 5,293,875. Applicants respectfully traverse. Claim 34 depends from claim 14. Again, the deficiencies of Otterbein with respect to claim 14 were discussed above in detail and Stone fails to remedy those deficiencies. Stone describes, *inter alia*, an apparatus, sampling methods and analysis techniques for measuring the concentration of end-tidal concentration of carbon monoxide in a patient's breath (see Stone at col. 2, lines 53 to 57). Stone, like Aldrich, fails to provide the information missing from Otterbein, nor would it have provided skilled practitioners with any motivation or reason to modify Otterbein in an attempt to arrive at the present invention. Thus, the combination of Otterbein and Stone do not support a *prima facie* case of obviousness and the rejection should be withdrawn.

CONCLUSION

Applicants request that all claims be allowed. This Reply is being filed along with an RCE and a Petition for Extension of Time for a one-month extension. The fees for the RCE (\$810), Petition (\$120) and excess claims (\$810) are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any

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other charges or credits to Deposit Account No. 06-1050, referencing attorney docket no.
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Respectfully submitted,

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